K131704

SUN NUCLEAR corporation

Your Most Valuable QA & Dosimetry Tools

510(k) Summary

Provided in accordance with 21 CFR 807.92 (c)

1 General Provisions

Date Prepared:

June 7, 2013

Submitted by:

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AUG 0 5 2013

Contact Person:

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Classification Name:

Accelerator, Linear, Medical

Common Name:

Dosimetric Quality Assurance for Patient Specific Radiation Treatment

Proprietary Names:

Model 1214 EPIDose

Establishment Registration Number:

1038814

Classification:

Regulation Number: 21 CFR 892.5050
Name: Medical charged-particle radiation therapy system, dosimetric quality control system
Product code: IYE

Predicate Device:

Model Name:	RIT113 Film Analysis System
Common Name:	Film Scanning System
510(k) #	K935928
Manufacturer:	Radiation Imaging Technology
Submitted:	Dec 7, 1993

2 Description and Use:

Sun Nuclear EPIDose product, model 1214, is a software application that converts electronic portal imaging device (EPID) image data -acquired by a third party treatment delivery device (TDD)- to a dose distribution which can subsequently be compared with the planned dose distribution for radiation therapy quality assurance purposes. From this comparison of the EPIDose result to the planned dose, a qualified clinician makes the decision whether the TDD along with its accessories (including the treatment planning system, or TPS) is capable of delivering the treatment as prescribed.

3 Intended Use Statement:

Sun Nuclear Corporation (SNC) Model 1214 EPIDose has the following intended use:

> Model 1214 EPIDose is a radiotherapy beam QA software application intended for two-dimensional (2D) electronic portal imaging device (EPID) image conversion to a phantom dose distribution for the purpose of comparison with a simulated dose distribution in the same phantom geometry as calculated by the treatment planning system (TPS).
>
> EPIDose is indicated for radiotherapy beam QA of radiotherapy treatment plans delivered on any treatment delivery device with an EPID that outputs DICOM-compliant images.

Apart from format and language refinement, the intended use statements are substantively the same for EPIDose and the predicate device.

4 Technological Characteristics

The significant technological characteristic of EPIDose is the patented method for image to dose conversion, where the image is created by an amorphous silicon (a-Si) array produced in a third-party EPID (US Patent # 8,130,905, March 6, 2012, "Dosimetry System and Method for Radiation Therapy"). The information density and spatial resolution of the dose distribution are comparable to that of film, while the durability, repeatability and accuracy are comparable to that of the dosimetric diode array.

The predicate device utilizes film for its radiation detector, which also provides a high spatial resolution and a large area that enables measurement of dose distributions that have high dose gradients found in radiotherapy deliveries. The film must be used in conjunction with a known phantom to simulate the correct radiologic characteristics. When this film is exposed to radiation from a radiation therapy beam and then developed, the result is that the film exhibits an increased optical density. When a film is exposed by a patient radiation therapy treatment plan, this optical density can then be converted to a dose distribution as would be delivered by that radiation therapy treatment.

5 Performance Data and Comparison with Predicate

EPIDose performance was verified using measurements internally performed as well as through reference. EPIDose and film results were compared for various clinical and non-clinical cases. For effective comparison of the data sets, gamma analysis was applied using a minimal pass rate of 68% with a 3.5% dose difference and 3.5 mm distance-to-agreement (DTA) tolerance, as recommended by report number 83 of the International Commission on Radiation Units and Measurements (ICRU). The pass rates for all cases were above 94%, greatly exceeding the recommended ICRU level. Given gamma analysis is a currently accepted scientific method for comparing two radiotherapy data sets and given the high level of agreement between EPIDose and film results, it is concluded that these results support a substantial equivalence determination with the predicate device.

6 Summary

The Model 1214 EPIDose intended use, performance testing, safety and effectiveness reviews demonstrate that this device is as safe, as effective, and performs as well or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 5, 2013

Sun Nuclear Corporation
% Jeff Kapatoes
3275 Suntree Blvd.
MELBOURNE, FL 32940

Re: K131704
Trade/Device Name: Model 1214 EPIDose
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: June 7, 2013
Received: June 11, 2013

Dear Mr. Kapatoes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must *comply* with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael O. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131704

Device Name: Model 1214 EPIDose

Indications for Use:

Model 1214 EPIDose is a radiotherapy beam QA software application intended for two-dimensional (2D) electronic portal imaging device (EPID) image conversion to a phantom dose distribution for the purpose of comparison with a simulated dose distribution in the same phantom geometry as calculated by the treatment planning system (TPS).

EPIDose is indicated for radiotherapy beam QA of radiotherapy treatment plans delivered on any treatment delivery device with an EPID that outputs DICOM-compliant images.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ___ _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K131704